

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

021186-001520US

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on Dec. 12, 2005Signature JM SmolenTyped or printed name Jennifer M. Smolen

Application Number

10/692,424

Filed

October 22, 2003

First Named Inventor

John Miller

Art Unit

8368

Examiner

James F. Hook

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s). **PLEASE SEE THE ATTACHED SHEETS.**

Note: No more than five (5) pages may be provided.

I am the

applicant/inventor.

assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

attorney or agent of record.

Registration number 52,182

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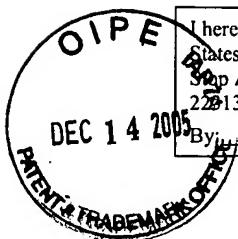
Registration number if acting under 37 CFR 1.34. _____

12/12/05

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

*Total of 1 forms are submitted.



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By: JM Grover

PATENT
Attorney Docket No.: 021186-001520US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

MILLER, John *et al.*

Application No.: 10/692,424

Filed: October 22, 2003

For: BALLOON CATHETER

Customer No.: 20350

Confirmation No. 8368

Examiner: HOOK, JAMES F

Technology Center/Art Unit: 3754

PRE-APPEAL BRIEF REQUEST
FOR REVIEW

Mail Stop AF, Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants offer this Pre-Appeal Brief Request for Review, for review of the present application under the Patent Pre-Appeal Brief Conference Pilot Program. The request, along with the below listed Remarks, is being submitted in conjunction with a Notice of Appeal (attached separately). Appendix A, attached hereto, contains a copy of all claims pending in this case.

SUMMARY OF THE INVENTION

Claim 1, the only independent claim, describes a catheter comprising a catheter body including at least one polymeric tubular member and a braided tubular structure comprising a plurality of component tubular members each having longitudinal lumens, woven radially in and out to form the braided tubular structure, wherein the braided tubular structure is embedded in a wall of the polymeric tubular member. As set forth, for example in claim 9, the catheter can further comprise a balloon on the catheter body connected to exchange inflation media through the lumens of the braided tubular structure. The catheter of the invention provides advantages over existing devices, for example, in that inflation media can be passed through the lumens of each of the braided tubular structure embedded in the catheter wall and can be used for inflating/deflating a balloon or inflatable member on the catheter body, thereby providing a balloon catheter with a large working lumen.

ARGUMENT

In the Final Office Action mailed August 8, 2005, claims 1, 2, 6, and 7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Steen (U.S. Patent No. 6,213,995) in view of Mische (U.S. Patent No. 5,052,105). Applicants respectfully traverse this rejection.

Applicants generally agree with the Examiner's characterization of Steen, but disagree that it would have been *prima facie* obvious to combine Steen with Mische, or that any reasonable combination of the references would produce the claimed invention. See, e.g., MPEP §§ 2142-2143. In particular, Applicants submit that the Examiner has failed to identify the requisite motivation or suggestion to replace the solid signal transmitting elements in the braid structure of Steen with hollow microtubes taught by Mische. Furthermore, the proposed combination Steen and Mische still would not produce the claimed invention because the combination would not produce the braided tubular structure as recited in claim 1.

Steen teaches an electrode catheter having a central lumen and a braid reinforcement structure within the catheter wall. The braid structure of Steen includes a braided combination of 1) structural elements, which provide stiffness and rigidity to the catheter; and 2) solid signal transmitting elements, including either electrically insulated, solid metal conductive wires, or solid optical fibers (e.g., glass). As acknowledged by the Examiner, nowhere does Steen teach or suggest a braided tubular structure comprising a plurality of component tubular members, as required by claim 1. (see, e.g., Final Office Action dated August 8, 2005, page 3). To overcome this deficiency, the Examiner argues that Mische teaches that, in general, it is "old and well known in the art" to substitute hollow tubes in place of conductive wires (see, e.g., Office Action mailed August 8, 2005, pages 3 and 4) and, therefore, it would have been obvious to combine the teachings of Steen and Mische. Applicants respectfully disagree.

Nothing in Mische supports Examiner's argument that, in general, selectively replacing solid conductive wires with hollow tubes is "old and well known". Mische teaches an interconnect cable which is a single, multiconductor cable constructed for connection to interconnect zones of an integrated circuit. The primary embodiments of Mische include solid metal or glass microcables for electrical or optical signal transduction. While Mische also teaches an alternate microcable embodiment where hollow tubes are used, e.g., to transmit pressure, nothing in Mische suggests a general desirability of hollow tubes compared to solid conductive wires or that those

elements are even "interchangeable", and there is certainly no suggestion that selectively replacing solid conductive wires with hollow tubes, in any context, is "old and well known".

Furthermore, while Mische teaches that the interconnect cable can be positioned inside a catheter lumen and used for transmitting a signal from a distal end of a catheter to a proximal connector, there is no remote suggestion in Mische that hollow tubes could find use in a catheter wall or a braid reinforcement structure of a medical catheter. In contrast to the solid braid embedded in a catheter wall as taught by Steen, Mische teaches that the interconnect cable is specifically designed for insertion into a catheter lumen (see, e.g., Mische col 3, lns 1-2). Thus, the combination proposed by the Examiner appears to be a result of impermissible hindsight construction based primarily on the Applicants disclosure, rather than the cited references or in the knowledge in the art. *In re Vaeck*, 20 U.S.P.Q.2d 1438 (CAFC 1991).

Regardless of motivation, the proposed combination Steen and Mische still would not produce the claimed invention because the combination would not produce the braided tubular structure as recited in claim 1. As set forth above, the braid reinforcement structure of Steen includes a braided combination of solid structural elements and solid signal-transmitting elements. The combination of elements of Steen and Mische proposed by the Examiner would, at best, produce a braided combination of solid structural elements and hollow tubes, but would not produce the braided tubular structure, as recited in claim 1.

Accordingly, the Examiner has not met the burden necessary for establishing *prima facie* obviousness. For these reasons, Applicants request that the rejection of claims 1, 2, 6, and 7 be withdrawn and the claims be allowed.

Claims 1-9 were also rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Samson (U.S. Patent No. 6,186,978) in view of Mische (U.S. Patent No. 5,052,105). Applicant respectfully traverses this rejection.

Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness because the Examiner has failed to identify the requisite motivation to make the proposed modification/combination of the cited references. In particular, nothing in the cited references teaches or suggests replacing the solid braid reinforcement structure of Sampson with the hollow micro-tubes of Mische.

Sampson is directed to a braid reinforced tubular catheter, wherein the catheter body includes an inner and an outer tubing assembly separated by an annular space, and a conventional solid braid reinforcement(s) integrated in between the assemblies. Rather than providing a braided tubular structure embedded in a wall of the polymeric tubular member, as required by claim 1, Sampson teaches the solid braid reinforcement that is specifically designed to provide structural support for the catheter and protection against unwanted kinking of the tubing wall (see, e.g., col. 4, lines 46-49, 55-64;).

The Examiner attempts to remedy the deficiency of Sampson by combining the teachings of Sampson with Mische. In particular, the Examiner argues that it would have been obvious to replace the solid braid reinforcement of Sampson with the hollow micro-tubes of Mische because 1) Mische teaches that substituting hollow tubes in place of electrical conductive wires is "old and well known in the art" since hollow tubes provide an equally useful "conductive means"; and 2) because the Mische tubes would provide "another means to transport something from one end of the catheter to the other which would expand the usefulness of the product..."

Applicants respectfully disagree. First, as set forth above, the Examiner's position that, in general, substituting hollow conductive tubes for solid electrical conductive wires is "old and well known" wholly lacks support in Mische or elsewhere (see above).

Second, the braided support in Sampson is designed and used for structural support, not for conducting electricity and, therefore, there would be no reason to replace the braided support with another "conductive means". While the solid braid reinforcements of Sampson may include metal, the braid reinforcements are support structures for protection against unwanted kinking of the tubing wall. In operation of the Sampson device, fluid is passed through the annular space, in contact with the interstices of the solid braid reinforcement structure, and into the balloon (see, e.g., col 5, lines 1-3). Transmission of an electrical current through the solid braid reinforcement is neither contemplated by Samson, nor is it plausible due to the configuration of the catheter device (e.g., fluid contacting the solid braid reinforcement structure). Thus, there would be no reason or motivation to replace the braided support of Samson with another "conductive means" because the braided support in Sampson is not used for conducting electricity in the first place.

It is further alleged that substituting the solid braid structure of Samson with hollow tubes of Mische would have been obvious because such a substitution would have provided "another

means" to transport something along the catheter, thereby making the catheter more versatile and valuable (see, e.g., Office Action mailed August 8, 2005, page 4). However, nothing in the record, separate from the present application, provides any remote suggestion or motivation for making the proposed combination. There is no suggestion in Samson that "another means" of transport, in addition to those already provided (i.e., catheter lumen, annular space), is necessary or desired. There is no suggestion in Mische or Steen that tubular conductors would find use in the wall of a catheter or a braid reinforcement. Moreover, the fact that the braid reinforcement of Samson is designed and used for increasing structural integrity of the catheter teaches away from the Examiner's suggested replacement of the solid braid of Samson with hollow wires because such a modification would actually reduce the tensile strength of the braid thereby, reducing the desired structural support. Thus, the combination argued by the Examiner again appears to result from impermissible hindsight reconstruction based purely on the teachings of the present invention, and lacks support in the sighted references.

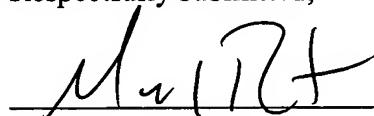
As such, for the reasons set forth above, *prima facie* obviousness has not been established. Accordingly, withdrawal of the rejection of claims 1-9 under 35 U.S.C. § 103(a) is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Respectfully submitted,

Date: 12/12/05



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APPENDIX

Pending Claims:

1. (Previously presented) A catheter comprising;
a catheter body comprising at least one polymeric tubular member; and
a braided tubular structure comprising a plurality of component tubular members each having longitudinal lumens, woven radially in and out to form said braided tubular structure, wherein said braided tubular structure is embedded in a wall of the polymeric tubular member.
2. (Previously presented) The catheter of claim 1, wherein the component tubular members are comprised of polymeric tubing.
3. (Previously presented) The catheter of claim 1, wherein the component tubular members are comprised of metallic tubing.
4. (Previously presented) The catheter of claim 3, where the metallic tubing comprises a superelastic alloy.
5. (Previously presented) The catheter of claim 4, wherein the superelastic alloy comprises nickel and titanium.
6. (Previously presented) The catheter of claim 1, wherein the at least one polymeric tubular member is disposed over said braided tubular structure.
7. (Previously presented) The catheter of claim 6, wherein said catheter body is of a size and shape suitable for introduction into a human blood vessel.
8. (Previously presented) The catheter of claim 1, where said plurality of component tubular members longitudinal lumens are fluidly connected to a plenum at least one of the distal and proximal ends.
9. (Previously presented) The catheter of claim 1, further comprising a balloon on the catheter body connected to exchange inflation media through the lumens of the braided tubular structure.